

Message Text

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PAGE 01 STATE 070713
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INFO OCT-01 EUR-12 ISO-00 OES-06 EB-08 /033 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/NE:JPSHUMATE(INFO)

-----310602Z 080595 /15

P 302357Z MAR 77
FM SECSTATE WASHDC
TO AMEMBASSY LONDON PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, OTRA, ETRD, EIND, TBIO, UK

SUBJECT: FDA REPRESENTATIVES PROVIDING TECHNICAL
AND CONSULTATIVE ASSISTANCE TO FOREIGN NON-CLINICAL
LABORATORIES

1. FDA ADVISES THAT:

MR. WALTER HANSEN-PHARMACOLOGIST, BUREAU OF DRUGS
DR. JAMES BURNS-PHARMACOLOGIST, BUREAU OF DRUGS
MRS. ESTELLA BARRY-PHARMACOLOGIST, BUREAU OF DRUGS
MR. PHILIP BRODSKY-INVESTIGATOR, EXECUTIVE DIRECTOR OF
REGIONAL OPERATIONS
MR. DAVID DUNCAN-INVESTIGATOR, DETROIT DISTRICT OFFICE
MR. DARYL J. THOMPSON-INVESTIGATOR, BOSTON DISTRICT OFFICE

WILL BE IN ENGLAND APRIL 21-MAY 20, 1977.

2. FDA REPRESENTATIVES WILL PERFORM AN ON-SITE DATA
AUDIT OF 3 NON-CLINICAL TESTING LABORATORIES IN ORDER TO
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DETERMINE THE ABILITY OF THESE LABORATORIES TO ADHERE TO
GOOD LABORATORY PRACTICE REGULATIONS AS PROPOSED IN THE

FEDERAL REGISTER DATED NOVEMBER 19, 1976. THIS TRIP
WILL BE THE FIRST TO BE PERFORMED UNDER THESE REGU-
LATIONS AND WILL AUDIT DATA SUBMITTED IN SUPPORT OF
NEW DRUG APPLICATIONS SUBMITTED BY SPONSORS TO FDA.

3. ITINERARY AS FOLLOWS:

APRIL 19: DEPART WASHINGTON, D.C. FOR LONDON, ENGLAND

APRIL 25-MAY 20: VISIT:

- (A) HUNTINGDON RESEARCH CENTRE, OXFORD
- (B) BOOTS PURE DRUG COMPANY, NOTTINGHAM
- (C) ALLEN AND HANBURY, WARE

MAY 23: DEPART LONDON FOR WASHINGTON, D.C.

4. WHILE IN LONDON PRIOR TO EMBARKING UPON DATA AUDITS, MR. BRODSKY (TEAM LEADER) AND PERHAPS SENIOR PHARMACOLOGIST PROPOSE:

(A) TO MEET WITH SCIENCE REPRESENTATIVE ON APRIL 21 AT EMBASSY TO DISCUSS REGULATIONS IN DETAIL AND PROPOSED PROGRAM OF DATA AUDITING OF FOREIGN NON-CLINICAL LABORATORIES.

(B) TO MEET WITH COUNTERPARTS OF MEDICINES DIVISION, DEPARTMENT OF HEALTH AND SOCIAL SECURITY ON APRIL 22 TO DISCUSS REGULATIONS, THEIR IMPLEMENTATION, AND IMPACT UPON "NEW DRUG" APPROVAL PROCESS AND IN PARTICULAR UPON DATA SUBMITTED TO NDA'S EITHER APPROVED OR IN APPROVAL PROCESS.

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FDA WOULD APPRECIATE POST MAKING APPROPRIATE APPOINTMENTS ON SPECIFIED DAYS (APRIL 21, 22) AND CONFIRMING THESE BY TELEX INDICATING NAMES OF CONCERNED INDIVIDUALS AND TIMES AND SITES OF CONFERENCES.
CHRISTOPHER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: TECHNICAL ASSISTANCE, MEDICAL FACILITIES, CONSULTANTS
Control Number: n/a
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Decaption Note:
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Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE070713
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770110-0126
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
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Legacy Key: link1977/newtext/t1977035/aaaaaehq.tel
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Litigation Code IDs:
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Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
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Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 20-Sep-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3079736
Secure: OPEN
Status: NATIVE
Subject: FDA REPRESENTATIVES PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO FOREIGN NON-CLINICAL LABORATORIES
TAGS: OGEN, OTRA, ETRD, EIND, TBIO, UK
To: LONDON
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/ad1d7db6-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009